S. 515

To amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to provide for improved public health and food safety through the reduction of harmful substances in meat and poultry that present a threat to public health, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 7 (legislative day, MARCH 6), 1995

Mr. Bradley introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

A BILL

To amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to provide for improved public health and food safety through the reduction of harmful substances in meat and poultry that present a threat to public health, and for other purposes.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.
- 4 (a) Short Title.—This Act may be cited as the
- 5 "Family Food Protection Act of 1995".
- 6 (b) Table of Contents.—The table of contents of
- 7 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings.

TITLE I-MEAT INSPECTION

- Sec. 101. References to the Federal Meat Inspection Act.
- Sec. 102. Definitions.
- Sec. 103. Inspection of meat and meat food products.
- Sec. 104. Post mortem examination of carcasses and marking or labeling.
- Sec. 105. Storage and handling regulations.
- Sec. 106. Federal and State cooperation.
- Sec. 107. Auxiliary provisions.
- Sec. 108. Reducing adulteration of meat and meat food products.

TITLE II—POULTRY INSPECTION

- Sec. 201. References to the Poultry Products Inspection Act.
- Sec. 202. Definitions.
- Sec. 203. Federal and State cooperation.
- Sec. 204. Ante mortem and post mortem inspection, reinspection, and quarantine.
- Sec. 205. Exemptions.
- Sec. 206. Reducing adulteration of poultry and poultry products.

1 SEC. 2. FINDINGS.

- 2 Congress finds that—
- 3 (1) bacterial foodborne illness exacts a terrible
- 4 toll on United States citizens, taking approximately
- 5 9,000 lives each year and causing between 6,500,000
- 6 and 80,000,000 illnesses;
- 7 (2) meat and meat food products, and poultry
- 8 and poultry products, contaminated with pathogenic
- 9 bacteria are a leading cause of foodborne illness;
- 10 (3) foodborne illness related to meat and poul-
- try cost Americans between \$2,000,000,000 and
- \$4,000,000,000 each year in medical expenses and
- lost wages;
- 14 (4) the number of illnesses and deaths associ-
- ated with adulterated meat and poultry undermines

- public confidence in the food supply of the United States and tends to destroy both domestic and foreign markets for wholesome meat and poultry;
 - (5) the meat and poultry inspection system costs United States taxpayers approximately \$600,000,000 per year but does not provide adequate protection against foodborne illness because the system does not test for and limit the presence of disease-causing bacteria;

(6) the Federal Government must—

- (A) set levels of disease-causing bacteria above which meat and meat food products and poultry and poultry products are determined to be unsafe for human consumption and adulterated; and
- (B) remove the products from commerce unless and until the products are made safe;
- (7) beginning with the National Academy of Sciences report entitled "Meat and Poultry: The Scientific Basis for the Nation's Program", the United States Department of Agriculture has been urged to shift from organoleptic inspection to inspection based on the detection and limitation of disease-causing bacteria;

| 1 | (8) to sustain the confidence of the people of |
|----|--|
| 2 | the United States and justify the expenditure of tax |
| 3 | dollars, the inspection system must— |
| 4 | (A) be based on sound application of mod- |
| 5 | ern science; |
| 6 | (B) effectively protect human health; |
| 7 | (C) be open to public scrutiny; |
| 8 | (D) create incentives for high standards; |
| 9 | (E) provide for fines for failure to meet |
| 10 | standards; and |
| 11 | (F) assess severe penalties for intentional |
| 12 | violation of the law; |
| 13 | (9) a modern system of meat and poultry in- |
| 14 | spection should extend from farm to table and re- |
| 15 | quire livestock and poultry producers, handlers, |
| 16 | processors, distributors, transporters, and retailers |
| 17 | to assume responsibility for handling livestock, meat, |
| 18 | meat food products, poultry, and poultry products in |
| 19 | such a way as to limit contamination to a level that |
| 20 | will not endanger human health; |
| 21 | (10) to effectively protect human health, there |
| 22 | must be an orderly transition from the system of in- |
| 23 | spection in effect on the date of enactment of this |
| 24 | Act to a new system based on preventive controls |
| 25 | that are designed to limit the presence of disease- |

- causing bacteria on meat, meat food products, poultry, and poultry products, and the efficacy of the new system must be demonstrated by pilot projects;
 - (11)(A) consumer confidence is further undermined by the "USDA Inspected and Passed" seal that appears on every package of meat or a meat food product and the "USDA Inspected for Wholesomeness" seal that appears on every package of poultry and poultry products, a seal that misleads consumers into believing the products are safe when the products often are contaminated with disease-causing bacteria; and
 - (B) the Federal Government should not affix a seal that misleads consumers and may increase the incidence of foodborne illness and death; and
 - (12)(A) all articles and other animals that are subject to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (21 U.S.C. 451 et seq.) are in interstate or foreign commerce or substantially affect commerce; and
 - (B) regulation by the Secretary of Agriculture and cooperation by the States, consistent with this Act and the amendments made by this Act, are necessary to prevent or eliminate burdens on commerce

- and to protect the health and welfare of consumers
- 2 of the United States.

3 TITLE I—MEAT INSPECTION

- 4 SEC. 101. REFERENCES TO THE FEDERAL MEAT INSPEC-
- 5 TION ACT.
- 6 Whenever in this title an amendment or repeal is ex-
- 7 pressed in terms of an amendment to, or repeal of, a sec-
- 8 tion or other provision, the reference shall be considered
- 9 to be made to a section or other provision of the Federal
- 10 Meat Inspection Act (21 U.S.C. 601 et seq.), except to
- 11 the extent otherwise specifically provided.
- 12 SEC. 102. DEFINITIONS.
- 13 (a) ADULTERATED.—Section 1(m)(1) (21 U.S.C.
- 14 601(m)(1) is amended to read as follows:
- 15 "(1) if it bears or contains a poisonous or dele-
- terious substance that may render it injurious to
- health, except that, in the case of a substance that
- is not an added substance, the article shall be con-
- sidered adulterated under this subsection if there is
- a reasonable probability that the quantity of the sub-
- stance in the article will cause adverse health con-
- sequences;".
- 23 (b) Added Substance; Official Establish-
- 24 MENT.—Section 1 is amended by adding at the end the
- 25 following:

| 1 | "(w) The term 'added substance'— |
|----|--|
| 2 | "(1) means a substance that is not an inherent |
| 3 | constituent of a food and whose intended use results |
| 4 | or may reasonably be expected to result, directly or |
| 5 | indirectly, in the substance becoming a component |
| 6 | of, or otherwise affecting the characteristics of, the |
| 7 | food; and |
| 8 | "(2) includes— |
| 9 | "(A) a substance that is intentionally |
| 10 | added to any food; or |
| 11 | "(B) a substance that is the result of mi- |
| 12 | crobial, viral, environmental, agricultural, in- |
| 13 | dustrial, or other contamination. |
| 14 | "(x) The term 'official establishment' means an es- |
| 15 | tablishment at which inspection of the slaughter of cattle |
| 16 | sheep, swine, goats, mules, and other equines, or the proc- |
| 17 | essing of meat and meat food products of the animals |
| 18 | is maintained in accordance with this Act.". |
| 19 | SEC. 103. STORAGE AND HANDLING REGULATIONS. |
| 20 | The last sentence of section 24 (21 U.S.C. 624) is |
| 21 | amended by inserting before the period at the end the fol- |
| 22 | lowing: ", except that regulations issued under section 503 |
| 23 | shall apply to a retail store or other type of retail estab- |
| 24 | lishment''. |

SEC. 104. FEDERAL AND STATE COOPERATION. 2 Section 301(c) (21 U.S.C. 661(c)) is amended— 3 (1) in paragraph (1)— 4 (A) in the first sentence— (i) by inserting after "the Wholesome 5 Meat Act," the following: "or by 30 days 6 prior to the expiration of the 2-year period 7 beginning on the date of enactment of the 8 Family Food Protection Act of 1995,"; 9 10 and (ii) by striking "title I and IV" and 11 inserting "titles I, IV, and V"; 12 (B) by striking "titles I and IV" each 13 place it appears and inserting "titles I, IV, and 14 V"; and 15 (C) by striking "title I and title IV" each 16 place it appears and inserting "titles I, IV, and 17 V"; and 18 19 (2) in paragraph (3), by striking "titles I and IV" each place it appears and inserting "titles I, IV, 20 21 and V". 22 SEC. 105. AUXILIARY PROVISIONS. Sections 402 and 403 (21 U.S.C. 672 and 673) are 23 amended by striking "title I or II" each place it appears 24 and inserting "title I, II, or V".

| 1 | SEC. 106. REDUCING ADULTERATION OF MEAT AND MEAT |
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| 2 | FOOD PRODUCTS. |
| 3 | The Act (21 U.S.C. 601 et seq.) is amended by add- |
| 4 | ing at the end the following: |
| 5 | "TITLE V—REDUCING ADULTER- |
| 6 | ATION OF MEAT AND MEAT |
| 7 | FOOD PRODUCTS |
| 8 | "SEC. 501. REDUCING ADULTERATION OF MEAT AND MEAT |
| 9 | FOOD PRODUCTS. |
| 10 | "(a) IN GENERAL.—On the basis of the best available |
| 11 | scientific and technological data, the Secretary shall issue |
| 12 | regulations to— |
| 13 | "(1) limit the presence of human pathogens and |
| 14 | other potentially harmful substances in cattle, sheep, |
| 15 | swine, or goats, or horses, mules, or other equines |
| 16 | at the time the animals are presented for slaughter; |
| 17 | "(2) ensure that appropriate measures are |
| 18 | taken to control and reduce the presence and growth |
| 19 | of human pathogens and other potentially harmful |
| 20 | substances on carcasses and parts of carcasses and |
| 21 | on meat or meat food products derived from the ani- |
| 22 | mals prepared in any official establishment; |
| 23 | "(3) ensure that all ready-to-eat meat or meat |
| 24 | food products prepared in any official establishment |
| 25 | preparing the meat or food product for distribution |
| 26 | in commerce are processed in such a manner as to |

| 1 | destroy any human pathogens and other potentially |
|----|--|
| 2 | harmful substances that are likely to cause |
| 3 | foodborne illness; and |
| 4 | "(4) ensure that meat and meat food products, |
| 5 | other than meat and meat food products referred to |
| 6 | in paragraph (3), prepared at any official establish- |
| 7 | ment preparing meat or a meat food product for dis- |
| 8 | tribution in commerce are labeled with instructions |
| 9 | for handling and preparation for consumption that, |
| 10 | when adhered to, will destroy any human pathogens |
| 11 | or other potentially harmful substances that are like- |
| 12 | ly to cause foodborne illness. |
| 13 | "(b) Noncompliance.— |
| 14 | "(1) In general.—Except as provided in para- |
| 15 | graph (2), a carcass or part of a carcass, or meat |
| 16 | or a meat food product, prepared at any official es- |
| 17 | tablishment preparing the article for distribution in |
| 18 | commerce, that is found not to be in compliance |
| 19 | with the regulations issued under paragraph (2), (3), |
| 20 | or (4) of subsection (a) shall be— |
| 21 | "(A) considered adulterated and deter- |
| 22 | mined to be condemned; and |
| 23 | "(B) if no appeal is made to the deter- |
| 24 | mination of condemnation, destroyed for human |

food purposes under the supervision of a duly authorized representative of the Secretary.

"(2) Reprocessing or labeling.—A carcass or part of a carcass, or meat or a meat food product that is not in compliance with paragraph (2), (3), or (4) of subsection (a), but that may by reprocessing or labeling, or both, be made not adulterated, need not be condemned and destroyed if after reprocessing or labeling, or both, as applicable and as determined by the Secretary, under the supervision of a duly authorized representative of the Secretary, the carcass, part of a carcass, meat, or meat food product is subsequently inspected and found to be not adulterated.

"(3) APPEALS.—

"(A) ACTION PENDING APPEAL.—If an appeal is made to a determination of condemnation, the carcass, part of a carcass, meat, or meat food product shall be appropriately marked, segregated, and held by the official establishment pending completion of an appeal inspection.

"(B) CONDEMNATION SUSTAINED.—If the determination of condemnation is sustained, the carcass, part of a carcass, meat, or meat food

| 1 | product if not so reprocessed or labeled, or |
|----|--|
| 2 | both, under paragraph (2) so as to be made not |
| 3 | adulterated, shall be destroyed for human food |
| 4 | purposes under the supervision of a duly au- |
| 5 | thorized representative of the Secretary. |
| 6 | "(c) Human Pathogens and Other Harmful |
| 7 | SUBSTANCES.—Not later than 1 year after the date of en- |
| 8 | actment of this title, the Secretary shall issue regulations |
| 9 | that— |
| 10 | "(1) require meat and meat food products in an |
| 11 | official establishment to be tested, in such manner |
| 12 | and with such frequency as the Secretary considers |
| 13 | necessary, to identify human pathogens, or markers |
| 14 | for the pathogens, and other potentially harmful |
| 15 | substances in the meat and meat food products; |
| 16 | "(2) require that the results of any test con- |
| 17 | ducted in accordance with paragraph (1) be reported |
| 18 | to the Secretary, in such manner and with such fre- |
| 19 | quency as the Secretary considers necessary; |
| 20 | "(3)(A) establish interim limits for human |
| 21 | pathogens and other potentially harmful substances |
| 22 | that, when found on meat or meat food products, |
| 23 | may present a threat to public health; and |

 $\lq\lq(B)$ in carrying out subparagraph (A)—

| 1 | "(i) establish interim limits that are below |
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| 2 | the industry mean as determined by the Sec- |
| 3 | retary for the pathogen or other potentially |
| 4 | harmful substance established through national |
| 5 | baseline studies; and |
| 6 | "(ii) reestablish the interim limits every |
| 7 | after the initial interim limits until the regu- |
| 8 | latory limits referred to in subsection $(d)(2)$, |
| 9 | tolerances, or other standards are established |
| 10 | under this Act or other applicable law; and |
| 11 | "(4) prohibit or restrict the sale, transpor- |
| 12 | tation, offer for sale or transportation, or receipt for |
| 13 | transportation of any meat or meat food products |
| 14 | that— |
| 15 | "(A) are capable of use as human food; |
| 16 | and |
| 17 | "(B) exceed the regulatory limits, interim |
| 18 | limits, tolerances, or other standards estab- |
| 19 | lished under this Act or other applicable law for |
| 20 | human pathogens or other potentially harmful |
| 21 | substances. |
| 22 | "(d) Research and Regulatory Limits.— |
| 23 | "(1) Research on food safety.—The Sec- |
| 24 | retary, acting through the Under Secretary of Agri- |

| 1 | culture for Food Safety, shall conduct or support ap- |
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| 2 | propriate research on food safety, including— |
| 3 | "(A) developing and reevaluating appro- |
| 4 | priate limits for human pathogens or other po- |
| 5 | tentially harmful substances that when found |
| 6 | on meat and meat food products prepared in of- |
| 7 | ficial establishments may present a threat to |
| 8 | public health; |
| 9 | "(B) developing efficient, rapid, and sen- |
| 10 | sitive methods for determining and detecting |
| 11 | the presence of microbial contamination, chemi- |
| 12 | cal residues, and animal diseases that have an |
| 13 | adverse impact on human health; |
| 14 | "(C) conducting baseline studies on the |
| 15 | prevalence of human pathogens or other poten- |
| 16 | tially harmful substances in processing facili- |
| 17 | ties; and |
| 18 | "(D) conducting risk assessments to deter- |
| 19 | mine the human pathogens and other poten- |
| 20 | tially harmful substances that pose the greatest |
| 21 | risk to human health. |
| 22 | "(2) Regulatory limits for human patho- |
| 23 | GENS AND OTHER HARMFUL SUBSTANCES.— |
| 24 | "(A) IN GENERAL.—Not later than 1 year |
| 25 | after the date of enactment of this title, the |

Secretary of Health and Human Services shall establish regulatory limits, to the maximum extent scientifically supportable, for human pathogens and other potentially harmful substances, including heavy metals, that, when found as a component of meat or meat food products prepared in official establishments, may present a threat to public health.

"(B) Risk to human health.—In establishing the regulatory limits, the Secretary of Health and Human Services shall consider the risk to human health, including the risk to children, the elderly, individuals whose immune systems are compromised, and other population subgroups, posed by consumption of the meat or meat food products containing the human pathogen or other potentially harmful substance.

"(C) Funding.—The Secretary of Agriculture shall annually transfer to the Secretary of Health and Human Services an amount, to be determined by the Secretaries, to defray the cost of establishing the regulatory limits.

"(e) SURVEILLANCE AND SAMPLING SYSTEMS.—

"(1) SURVEILLANCE SYSTEM.—In conjunction with the Director of the Centers for Disease Control and Prevention and the Commissioner of Food and Drugs, the Secretary shall develop and administer an active surveillance system for foodborne illness, that is based on a representative sample of the population of the United States, to assess more accurately the frequency and sources of human disease in the United States associated with the consumption of food products.

"(2) Sampling System.—

"(A) In general.—Not later than 2 years after the date of enactment of this title, the Secretary shall establish a sampling system, using data collected under subsection (c)(2) and other sources, to analyze the nature, frequency of occurrence, and quantities of human pathogens and other potentially harmful substances in meat and meat food products.

"(B) Information.—The sampling system shall provide—

"(i) statistically valid monitoring, including market basket studies, on the nature, frequency of occurrence, and quantity of human pathogens and other potentially harmful substances in meat and meat food products available to consumers; and

> "(ii) such other information as the Secretary determines may be useful in assessing the occurrence of human pathogens and other potentially harmful substances in meat and meat food products.

"(C) Noncompliance.—If a sample is found to exceed regulatory limits, interim limits, tolerances, or standards established under this Act or other applicable law, the Secretary shall take action to prevent violative products from entering commerce or to remove the violative products from the market.

"(f) REVIEW AND CONSULTATION.—

"(1) Review.—The Secretary shall review, at least 2 years, all regulations, processes, procedures, and methods designed to limit and control human pathogens and other potentially harmful substances present on or in carcasses and parts of carcasses and in meat and meat food products. The ongoing review shall include, as necessary, epidemiologic and other scientific studies to ascertain the efficiency and efficacy of the regulations, processes, procedures, and methods.

| 1 | "(2) Consultation.—In carrying out para- |
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| 2 | graphs (1) and (3) of subsection (c), subsection (d), |
| 3 | subsection (e)(1), and paragraph (1), the Secretary |
| 4 | shall consult with the Assistant Secretary for |
| 5 | Health, the Director of the Centers for Disease Con- |
| 6 | trol and Prevention, the Commissioner of Food and |
| 7 | Drugs, and the heads of such other Federal and |
| 8 | State public health agencies as the Secretary consid- |
| 9 | ers appropriate. |
| 10 | "SEC. 502. HAZARD CONTROLS. |
| 11 | "(a) Regulations.— |
| 12 | "(1) Issuance.—Not later than 1 year after |
| 13 | the date of enactment of this title, the Secretary |
| 14 | shall issue regulations that require an official estab- |
| | |
| 15 | lishment to— |
| 1516 | lishment to— "(A) adopt processing controls that are |
| | |
| 16 | "(A) adopt processing controls that are |
| 16 17 | "(A) adopt processing controls that are adequate to protect public health; and |
| 161718 | "(A) adopt processing controls that are adequate to protect public health; and "(B) limit the presence and growth of |
| 16 17 18 19 | "(A) adopt processing controls that are adequate to protect public health; and "(B) limit the presence and growth of human pathogens and other potentially harmful |
| 16 17 18 19 20 | "(A) adopt processing controls that are adequate to protect public health; and "(B) limit the presence and growth of human pathogens and other potentially harmful substances in carcasses and parts of carcasses |
| 16 17 18 19 20 21 | "(A) adopt processing controls that are adequate to protect public health; and "(B) limit the presence and growth of human pathogens and other potentially harmful substances in carcasses and parts of carcasses and on meat and meat food products derived |

| 1 | "(B) set interim limits for biological, |
|----|--|
| 2 | chemical, and physical hazards, as appropriate; |
| 3 | "(C) require processing controls to ensure |
| 4 | that relevant regulatory standards are met; |
| 5 | "(D) require recordkeeping to monitor |
| 6 | compliance; |
| 7 | "(E) require sampling to ensure that proc- |
| 8 | essing controls are effective and that regulatory |
| 9 | standards are being met; and |
| 10 | "(F) provide for agency access to records |
| 11 | kept by official establishments and submission |
| 12 | of copies of the records to the Secretary as the |
| 13 | Secretary considers appropriate. |
| 14 | "(3) Public access.—Public access to records |
| 15 | that relate to the adequacy of measures taken by an |
| 16 | official establishment to protect the public health, |
| 17 | and to limit the presence and growth of human |
| 18 | pathogens and other potentially harmful substances, |
| 19 | shall be subject to section 552 of title 5, United |
| 20 | States Code. |
| 21 | "(4) Processing controls.—The Secretary |
| 22 | may, as the Secretary considers necessary, require |
| 23 | any person with responsibility for, or control over, |
| 24 | any animals or meat or meat food products intended |
| 25 | for human consumption to adopt processing controls, |

| 1 | if the processing controls are needed to ensure the |
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| 2 | protection of public health. |
| 3 | "(b) Advisory Board.— |
| 4 | "(1) In General.—On the issuance of regula- |
| 5 | tions under subsection (a), the Secretary shall con- |
| 6 | vene an advisory board on meat and poultry safety |
| 7 | to— |
| 8 | "(A) recommend improvements to the |
| 9 | meat and poultry inspection programs; |
| 10 | "(B) evaluate alternatives to the programs; |
| 11 | and |
| 12 | "(C) provide other relevant advice to the |
| 13 | Secretary. |
| 14 | "(2) Composition.—The advisory board shall |
| 15 | include representatives of consumers, processors, |
| 16 | producers, retail outlets, inspectors, plant workers, |
| 17 | public health officials, and victims of foodborne ill- |
| 18 | ness. |
| 19 | "(3) DUTIES.—The advisory board shall— |
| 20 | ''(A) evaluate— |
| 21 | "(i) the meat and poultry inspection |
| 22 | programs; and |
| 23 | "(ii) the significance of the programs |
| 24 | in ensuring the proper operation of manda- |
| 25 | tory processing controls; and |

| 1 | "(B) make recommendations to the Sec- |
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| 2 | retary described in paragraph (4). |
| 3 | "(4) Report.—The Secretary shall report to |
| 4 | Congress on the recommendations of the advisory |
| 5 | board for improving the meat and poultry inspection |
| 6 | programs, including— |
| 7 | "(A) the timing and criteria for any |
| 8 | changes in the programs; |
| 9 | "(B) alternative approaches for addressing |
| 10 | safety and quality issues; and |
| 11 | $^{\prime\prime}(C)$ the minimum time needed to ensure |
| 12 | that processing controls effectively reduce |
| 13 | foodborne illness prior to any change in the |
| 14 | programs. |
| 15 | "(5) PROCEDURE.—The advisory board shall be |
| 16 | subject to the Federal Advisory Committee Act (5 |
| 17 | U.S.C. App.). |
| 18 | "(c) Labeling.—Notwithstanding any other provi- |
| 19 | sion of this Act, if the Secretary discontinues carcass-by- |
| 20 | carcass inspection of meat, the 'USDA Inspected and |
| 21 | Passed' seal, or a similar seal, shall not be affixed to any |
| 22 | carcasses and parts of carcasses and to meat and meat |
| 23 | food products derived from the animals prepared in any |
| 24 | official establishment. |

| 1 | "SEC. 503. VOLUNTARY GUIDELINES FOR RETAIL ESTAB- |
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| 2 | LISHMENTS. |
| 3 | "(a) Standards.— |
| 4 | "(1) IN GENERAL.—In consultation with rep- |
| 5 | resentatives of States, the Conference for Food Pro- |
| 6 | tection, the Association of Food and Drug Officials, |
| 7 | and Federal agencies, the Secretary shall establish |
| 8 | minimum standards for the handling, processing, |
| 9 | and storage of meat and meat food products at re- |
| 10 | tail stores, restaurants, and similar types of retail |
| 11 | establishments (collectively referred to in this section |
| 12 | as 'retail establishments'). |
| 13 | "(2) CONTENT.—The standards shall— |
| 14 | "(A) be designed to ensure that meat and |
| 15 | meat food products sold by retail establish- |
| 16 | ments are safe for human consumption; |
| 17 | "(B) be based on the principles of preven- |
| 18 | tive controls; and |
| 19 | "(C) include— |
| 20 | "(i) safe food product processing and |
| 21 | handling practices for retail establish- |
| 22 | ments, including time and temperature |
| 23 | controls on meat and meat food products |
| 24 | sold by the establishments; |
| 25 | "(ii) equipment handling practices, in- |
| 26 | cluding standards for the cleaning and |

| sanitization of food equipment and uten- |
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| sils; |
| "(iii) minimum personnel hygiene re- |
| quirements; and |
| "(iv) requirements for the use of tem- |
| perature warning devices on raw meat and |
| meat food products to alert consumers to |
| inadequate temperature controls. |
| "(b) Guidelines.— |
| "(1) ISSUANCE.—Not later than 18 months |
| after the date of enactment of this title, the Sec- |
| retary, after notice and opportunity for comment |
| shall issue guidelines for retail establishments that |
| offer meat and meat food products that include the |
| standards established under subsection (a). |
| "(2) Compliance.—Not later than 18 months |
| after the date of enactment of this title, the Sec- |
| retary shall issue a final regulation defining the cir- |
| cumstances that constitute substantial compliance by |
| retail establishments with the guidelines issued |
| under paragraph (1). The regulation shall provide |
| that there is not substantial compliance if a signifi- |
| cant number of retail establishments have failed to |
| comply with the guidelines. |
| |

"(3) Report.—

"(A) IN GENERAL.—Not later than 3 years after the date of enactment of this title, the Secretary shall issue a report to Congress on actions taken by retail establishments to comply with the guidelines. The report shall include a determination of whether there is substantial compliance with the guidelines.

"(B) SUBSTANTIAL COMPLIANCE.—If the Secretary determines that there is substantial compliance with the guidelines, the Secretary shall issue a report and make a determination in accordance with subparagraph (A) not less than every 2 years.

"(C) No substantial compliance.—If the Secretary determines that there is not substantial compliance with the guidelines, the Secretary shall (at the time the determination is made) issue proposed regulations requiring that retail establishments comply with the guidelines. The Secretary shall issue final regulations imposing the requirement not later than 180 days after issuance of any proposed regulations. Any final regulations shall become effective 180 days after the date of the issuance of the final regulations.

- 1 "(c) Enforcement.—A State may bring, in the
- 2 name of the State and within the jurisdiction of the State,
- 3 a proceeding for the civil enforcement, or to restrain a vio-
- 4 lation, of final regulations issued pursuant to subsection
- 5 (b)(3)(C) if the food that is the subject of the proceeding
- 6 is located in the State.

7 "SEC. 504. LIVESTOCK TRACEBACK.

- 8 "(a) In General.—
- "(1) IDENTIFICATION.—For the purpose of un-9 10 derstanding the nature of foodborne illness and minimizing the risks of foodborne illness from car-11 casses and parts of carcasses and meat and meat 12 13 food products distributed in commerce, the Secretary 14 shall, as the Secretary considers necessary, prescribe 15 by regulation that cattle, sheep, swine, and goats, 16 and horses, mules, and other equines presented for 17 slaughter for human food purposes be identified in 18 a manner prescribed by the Secretary to enable the 19 Secretary to trace each animal to any premises at 20 which the animal has been held for such period prior to slaughter as the Secretary considers necessary to 21 22 carry out this Act.
 - "(2) PROHIBITION OR RESTRICTION ON ENTRY.—The Secretary may prohibit or restrict entry into any slaughtering establishment inspected

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- 1 under this Act of any cattle, sheep, swine, or goats,
- or horses, mules, or other equines not identified as
- 3 prescribed by the Secretary.
- 4 "(b) Records.—

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- "(1) IN GENERAL.—The Secretary may require that a person required to identify livestock pursuant to subsection (a) maintain accurate records, as prescribed by the Secretary, regarding the purchase, sale, and identification of the livestock.
 - "(2) Access.—A person subject to paragraph
 (1) shall, at all reasonable times, on notice by a duly
 authorized representative of the Secretary, afford
 the representative access to the place of business of
 the person and an opportunity to examine the
 records of the person and copy the records.
 - "(3) DURATION.—Any record required to be maintained under this subsection shall be maintained for such period of time as the Secretary prescribes.
- 20 "(c) False Information.—No person shall falsify
- 21 or misrepresent to the Secretary or any other person any
- 22 information concerning the premises at which any cattle,
- 23 sheep, swine, or goats, or horses, mules, or other equines,
- 24 or carcasses thereof, were held.

- 1 "(d) Maintenance of Records.—No person shall,
- 2 without authorization from the Secretary, alter, detach, or
- 3 destroy any records or other means of identification pre-
- 4 scribed by the Secretary for use in determining the prem-
- 5 ises at which were held any cattle, sheep, swine, or goats,
- 6 or horses, mules, or other equines, or the carcasses there-
- 7 of.
- 8 "(e) Human Pathogens or Other Harmful Sub-
- 9 STANCES.—
- 10 "(1) Identification of source.—If the Sec-11 retary finds any human pathogen or any other po-12 tentially harmful substance in any cattle, sheep, 13 swine, or goats, or horses, mules, or other equines 14 at the time they are presented for slaughter or in 15 any carcasses, parts of carcasses, meat, or meat food products prepared in an official establishment and 16 17 the Secretary finds that there is a reasonable prob-18 ability that human consumption of any meat or meat 19 food product containing the human pathogen or 20 other potentially harmful substance presents a threat to public health, the Secretary may take such 21 22 action as the Secretary considers necessary to determine the source of the human pathogen or other po-23

tentially harmful substance.

"(2) Action.—If the Secretary identifies the source of any human pathogen or other potentially harmful substance referred to in paragraph (1), the Secretary may prohibit or restrict the movement of any animals, carcasses, parts of carcasses, meat, meat food products, or any other article from any source of the human pathogen or other potentially harmful substance until the Secretary determines that the human pathogen or other potentially harmful substance at the source no longer presents a threat to public health.

"(f) Producers and Handlers.—

- "(1) USE OF METHODS.—The Secretary shall use any means of identification and recordkeeping methods utilized by producers or handlers of cattle, sheep, swine, or goats, or horses, mules, or other equines whenever the Secretary determines that the means of identification and recordkeeping methods will enable the Secretary to carry out this section.
- "(2) COOPERATION.—The Secretary may cooperate with producers or handlers of cattle, sheep, swine, or goats, or horses, mules, or other equines, in which any human pathogen or other potentially harmful substance described in subsection (e)(1) is found, to develop and carry out methods to limit or

| 1 | eliminate the human pathogen or other potentially |
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| 2 | harmful substance at the source. |
| 3 | "SEC. 505. NOTIFICATION AND RECALL OF NONCONFORM- |
| 4 | ING ARTICLES. |
| 5 | "(a) Notification.—Any person preparing car- |
| 6 | casses or parts of carcasses, meat, or meat food products |
| 7 | for distribution in commerce who obtains knowledge that |
| 8 | provides a reasonable basis for believing that any car- |
| 9 | casses or parts of carcasses or any meat or meat food |
| 10 | products— |
| 11 | "(1) are unsafe for human consumption, adul- |
| 12 | terated, or not produced in accordance with section |
| 13 | 501(a); or |
| 14 | "(2) are misbranded; |
| 15 | shall immediately notify the Secretary, in such manner |
| 16 | and by such means as the Secretary may by regulation |
| 17 | prescribe, of the identity and location of the articles. |
| 18 | "(b) Recall.— |
| 19 | "(1) IN GENERAL.—If the Secretary finds, on |
| 20 | notification or otherwise, that any carcasses or parts |
| 21 | of carcasses or any meat or meat food products— |
| 22 | "(A) are unsafe for human consumption, |
| 23 | adulterated, or not produced in accordance with |
| 24 | section 501(a); or |
| 25 | "(B) are misbranded; |

the Secretary shall by order require any person en-1 2 gaged in the processing, handling, transportation, storage, importation, distribution, or sale of the arti-3 cles to immediately cease any distribution of the articles, and to recall the articles from commercial dis-5 tribution and use, if the Secretary determines that 6 7 there is a reasonable probability that the product is unsafe for human consumption, adulterated, or mis-8 branded, unless the person is engaged in a voluntary 9 recall of the articles that the Secretary considers 10 11 adequate. "(2) ORDER.—The order shall— 12

- "(A) include a timetable during which the recall shall occur;
- "(B) require periodic reports by the person to the Secretary describing the progress of the recall; and
- "(C) require notice to consumers to whom the articles were, or may have been, distributed as to how the consumers should treat the article.

"(c) Informal Hearing.—

"(1) IN GENERAL.—The order shall provide any person subject to the order with an opportunity for an informal hearing, to be held not later than 5 days

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- after the date of issuance of the order, on the actions required by the order.
- "(2) VACATION OF ORDER.—If, after providing an opportunity for the hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.
- "(d) Judicial Recall.—A district court of the United States may order any person engaged in the processing, handling, transportation, storage, importation, distribution, or sale of any carcass, part of a carcass, meat, or meat food product to recall the carcass, part of a carcass, meat, or meat food product if the court finds that there is a reasonable probability that the carcass, part of
- 15 a carcass, meat, or meat food product is unsafe for human
- 16 consumption, adulterated, or misbranded.

17 "SEC. 506. REFUSAL OR WITHDRAWAL OF INSPECTION.

- 18 "(a) IN GENERAL.—The Secretary may, for such pe-
- 19 riod or indefinitely as the Secretary considers necessary
- 20 to carry out this Act, refuse to provide, or withdraw, in-
- 21 spections under title I with respect to any official estab-
- 22 lishment if the Secretary determines, after opportunity for
- 23 a hearing is accorded to the applicant for, or recipient of,
- 24 the service that the applicant or recipient, or any person

- 1 connected with the applicant or recipient, has repeatedly
- 2 failed to comply with this Act.
- 3 "(b) Inspections Pending Review.—The Sec-
- 4 retary may direct that, pending opportunity for an expe-
- 5 dited hearing in the case of any refusal or withdrawal of
- 6 inspections and the final determination and order under
- 7 subsection (a) and any judicial review of the determination
- 8 and order, inspections shall be denied or suspended if the
- 9 Secretary considers the action necessary in the public in-
- 10 terest in order to protect the health or welfare of consum-
- 11 ers or to ensure the safe and effective performance of offi-
- 12 cial duties under this Act.
- 13 "(c) Judicial Review.—
- 14 "(1) IN GENERAL.—The determination and
- order of the Secretary with respect to refusal or
- withdrawal of inspections under this section shall be
- final and conclusive unless the applicant for, or re-
- cipient of, inspections files an application for judicial
- review not later than 30 days after the effective date
- of the order.
- 21 "(2) Inspections pending review.—Inspec-
- tions shall be refused or withdrawn as of the effec-
- 23 tive date of the order pending any judicial review of
- the order unless the Secretary or the Court of Ap-
- peals directs otherwise.

| 1 | "(3) VENUE; RECORD.—Judicial review of the |
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| 2 | order shall be— |
| 3 | "(A) in the United States Court of Appeals |
| 4 | for the circuit in which the applicant for, or the |
| 5 | recipient of, inspections has the principal place |
| 6 | of business of the applicant or recipient or in |
| 7 | the United States Court of Appeals for the Dis- |
| 8 | trict of Columbia Circuit; and |
| 9 | "(B) based on the record on which the de- |
| 10 | termination and order are based. |
| 11 | "(4) Process.—Section 204 of the Packers |
| 12 | and Stockyards Act, 1921 (7 U.S.C. 194), shall be |
| 13 | applicable to appeals taken under this section. |
| 14 | "(d) Additional Authority.—This section shall be |
| 15 | in addition to, and not derogate from, any provision of |
| 16 | this Act for refusal, withdrawal, or suspension of inspec- |
| 17 | tions under title I. |
| 18 | "SEC. 507. CIVIL PENALTIES. |
| 19 | "(a) In General.— |
| 20 | "(1) Assessment.—A person who violates this |
| 21 | title, a regulation issued under this title, or an order |
| 22 | issued under subsection (b) or (d) of section 505 |
| 23 | may be assessed a civil penalty by the Secretary of |
| 24 | not more than \$100,000 for each day of violation. |

- "(2) SEPARATE VIOLATION.—Each offense described in paragraph (1) shall be considered to be a separate violation.
 - "(3) NOTICE AND OPPORTUNITY FOR HEAR-ING.—No penalty may be assessed against a person under this section unless the person is given notice and an opportunity for a hearing on the record before the Secretary in accordance with sections 554 and 556 of title 5, United States Code.
 - "(4) Amount.—The amount of the civil penalty shall be assessed by the Secretary by written order, taking into account the gravity of the violation, the degree of culpability, and any history of prior offenses. The amount may be reviewed only as provided in subsection (b).

"(b) REVIEW.—

"(1) IN GENERAL.—A person against whom a violation is found and a civil penalty assessed by order of the Secretary under subsection (a) may obtain review of the order in the United States Court of Appeals for the circuit in which the party resides or has a place of business or in the United States Court of Appeals for the District of Columbia Circuit by filing a notice of appeal in the court not later than 30 days after the date of the order and by si-

- multaneously sending a copy of the notice by certified mail to the Secretary.
- "(2) RECORD.—The Secretary shall promptly file in the court a certified copy of the record on which the violation was found and the penalty assessed.
 - "(3) FINDINGS.—The findings of the Secretary shall be set aside only if found to be unsupported by substantial evidence on the record as a whole.

"(c) CIVIL ACTION TO RECOVER ASSESSMENT.—

- "(1) IN GENERAL.—If a person fails to pay an assessment of a civil penalty after the penalty has become a final and unappealable order, or after the appropriate Court of Appeals has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General, who shall institute a civil action to recover the amount assessed in any appropriate district court of the United States.
- "(2) Scope of Review.—In a recovery action under paragraph (1), the validity and appropriateness of the order of the Secretary imposing the civil penalty shall not be subject to review.

| 1 | "(d) DISPOSITION OF AMOUNTS.—All amounts col- |
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| 2 | lected under this section shall be paid into the Treasury |
| 3 | of the United States. |
| 4 | "(e) Equitable Relief.— |
| 5 | "(1) Relationship to other actions.— |
| 6 | Nothing in this Act requires the Secretary to report |
| 7 | for criminal prosecution, or for the institution of an |
| 8 | injunction or other proceeding, a violation of this |
| 9 | Act, if the Secretary believes that the public interest |
| 10 | will be adequately served by assessment of civil pen- |
| 11 | alties. |
| 12 | "(2) Modification of Penalty.—The Sec- |
| 13 | retary may compromise, modify, or remit, with or |
| 14 | without conditions, any civil penalty assessed under |
| 15 | this section. |
| 16 | "SEC. 508. WHISTLEBLOWER PROTECTION. |
| 17 | "(a) In General.—No person subject to this Act |
| 18 | may harass, prosecute, hold liable, or discriminate against |
| 19 | any employee or other person because the person— |
| 20 | "(1) is assisting or demonstrating an intent to |
| 21 | assist in achieving compliance with any Federal or |
| 22 | State law (including a rule or regulation); |
| 23 | "(2) is refusing to violate or assist in the viola- |
| 24 | tion of any Federal or State law (including a rule or |
| 25 | regulation); or |

- "(3) has commenced, caused to be commenced, 1 2 or is about to commence a proceeding, has testified 3 or is about to testify at a proceeding, or has assisted or participated or is about to assist or participate in any manner in such a proceeding or in any other ac-6 tion to carry out the functions or responsibilities of any agency, office, or unit of the Department of Ag-7 riculture.
- "(b) Procedures and Penalties.—The procedures and penalties applicable to prohibited acts under 10 subsection (a) shall be governed by the applicable provisions of section 31105 of title 49, United States Code. "(c) BURDENS OF PROOF.—The legal burdens of 13 proof with respect to prohibited acts under subsection (a) 14 shall be governed by the applicable provisions of sections
- 1214 and 1221 of title 5, United States Code.". 16

TITLE II—POULTRY INSPECTION 17

- SEC. 201. REFERENCES TO THE POULTRY PRODUCTS IN-
- 19 SPECTION ACT.

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- 20 Whenever in this title an amendment or repeal is ex-
- pressed in terms of an amendment to, or repeal of, a sec-
- tion or other provision, the reference shall be considered
- to be made to a section or other provision of the Poultry
- Products Inspection Act (21 U.S.C. 451 et seq.), except
- to the extent otherwise specifically provided.

1 SEC. 202. DEFINITIONS.

| 2 | (a) ADULTERATED.—Section 4(g)(1) (21 U.S.C. |
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| 3 | 453(g)(1)) is amended to read as follows: |
| 4 | "(1) if it bears or contains a poisonous or dele- |
| 5 | terious substance that may render it injurious to |
| 6 | health, except that, in the case of a substance that |
| 7 | is not an added substance, the article shall be con- |
| 8 | sidered adulterated under this subsection if there is |
| 9 | a reasonable probability that the quantity of the sub- |
| 10 | stance in the article will cause adverse health con- |
| 11 | sequences;". |
| 12 | (b) ADDED SUBSTANCE.—Section 4 is amended by |
| 13 | adding at the end the following: |
| 14 | "(cc) The term 'added substance'— |
| 15 | "(1) means a substance that is not an inherent |
| 16 | constituent of a food and whose intended use results, |
| 17 | or may reasonably be expected to result, directly or |
| 18 | indirectly, in the substance becoming a component |
| 19 | of, or otherwise affecting the characteristics of, the |
| 20 | food; and |
| 21 | "(2) includes— |
| 22 | "(A) a substance that is intentionally |
| 23 | added to any food; or |
| 24 | "(B) a substance that is the result of mi- |
| 25 | crobial, viral, environmental, agricultural, in- |
| 26 | dustrial, or other contamination.". |

1 SEC. 203. FEDERAL AND STATE COOPERATION.

- The first sentence of section 5(c)(1) (21 U.S.C.
- 3 454(c)(1) is amended—
- 4 (1) by inserting after "the Wholesome Poultry
- 5 Products Act," the following: "or by 30 days prior
- 6 to the expiration of the 2-year period beginning on
- 7 the date of enactment of the Family Food Protection
- 8 Act of 1995,"; and
- 9 (2) by striking "sections 1–4, 6–10, and 12–22
- of this Act" and inserting "sections 1 through 4, 6
- through 10, 12 through 22, and 30 through 37".
- 12 SEC. 204. EXEMPTIONS.
- 13 Section 15(a)(1) (21 U.S.C. 464(a)(1)) is amended
- 14 by inserting before the semicolon at the end the following:
- 15 ", except that regulations issued under section 32 shall
- 16 apply to a retail store or other type of retail establish-
- 17 ment''.
- 18 SEC. 205. REDUCING ADULTERATION OF POULTRY AND
- 19 **POULTRY PRODUCTS.**
- The Act (21 U.S.C. 451 et seq.) is amended by add-
- 21 ing at the end the following:
- 22 "SEC. 30. REDUCING ADULTERATION OF POULTRY AND
- 23 **POULTRY PRODUCTS.**
- "(a) IN GENERAL.—On the basis of the best available
- 25 scientific and technological data, the Secretary shall issue
- 26 regulations to—

- "(1) limit the presence of human pathogens and other potentially harmful substances in poultry at the time the poultry are presented for slaughter;
 - "(2) ensure that appropriate measures are taken to control and reduce the presence and growth of human pathogens and other potentially harmful substances on poultry or poultry products prepared in any official establishment;
 - "(3) ensure that all ready-to-eat poultry or poultry products prepared in any official establishment preparing the poultry or poultry products for distribution in commerce are processed in such a manner as to destroy any human pathogens and other potentially harmful substances that are likely to cause foodborne illness; and
- "(4) ensure that poultry and poultry products, other than the poultry and products referred to in paragraph (3), prepared at any official establishment preparing the poultry or poultry products for distribution in commerce are labeled with instructions for handling and preparation for consumption that, when adhered to, will destroy any human pathogens or other potentially harmful substances that are likely to cause foodborne illness.
- "(b) Noncompliance.—

"(1) IN GENERAL.—Except as provided in paragraph (2), poultry or a poultry product prepared at any official establishment preparing the poultry or poultry product for distribution in commerce, that is found not to be in compliance with the regulations issued under paragraph (2), (3), or (4) of subsection (a) shall be—

"(A) considered adulterated and deter-

- "(A) considered adulterated and determined to be condemned; and
- "(B) if no appeal is made to the determination of condemnation, destroyed for human food purposes under the supervision of an inspector.
- "(2) Reprocessing or labeling.—Poultry or a poultry product that is not in compliance with paragraph (2), (3), or (4) of subsection (a), but that may by reprocessing or labeling, or both, be made not adulterated, need not be condemned and destroyed if after reprocessing or labeling, or both, as applicable and as determined by the Secretary, under the supervision of an inspector, the poultry or poultry product is subsequently inspected and found to be not adulterated.
- 24 "(3) APPEALS.—

1 "(A) ACTION PENDING APPEAL.—If an appeal is made to a determination of condemna-2 peal is made to a determination of condemna-3 tion, the poultry or poultry product shall be ap-4 propriately marked, segregated, and held by the 5 official establishment pending completion of an 6 appeal inspection.

- "(B) CONDEMNATION SUSTAINED.—If the determination of condemnation is sustained, the poultry or poultry product if not reprocessed or labeled, or both, under paragraph (2) so as to be made not adulterated, shall be destroyed for human food purposes under the supervision of a duly authorized representative of the Secretary.
- 15 "(c) Human Pathogens and Other Harmful 16 Substances.—Not later than 1 year after the date of en-17 actment of this section, the Secretary shall issue regula-18 tions that—
 - "(1) require poultry and poultry products in an official establishment to be tested, in such manner and with such frequency as the Secretary considers necessary, to identify human pathogens, or markers for the pathogens, and other potentially harmful substances in the poultry and poultry products;

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| 1 | "(2) require that the results of any test con- |
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| 2 | ducted in accordance with paragraph (1) be reported |
| 3 | to the Secretary, in such manner and with such fre- |
| 4 | quency as the Secretary considers necessary; |
| 5 | "(3)(A) establish interim limits for human |
| 6 | pathogens and other potentially harmful substances |
| 7 | that, when found on poultry or poultry products, |
| 8 | may present a threat to public health; and |
| 9 | "(B) in carrying out subparagraph (A)— |
| 10 | "(i) establish interim limits that are below |
| 11 | the industry mean as determined by the Sec- |
| 12 | retary for the pathogen or other potentially |
| 13 | harmful substance established through national |
| 14 | baseline studies; and |
| 15 | "(ii) reestablish the interim limits every |
| 16 | two years after the initial interim limits until |
| 17 | the regulatory limits referred to in subsection |
| 18 | (d)(2), tolerances, or other standards are estab- |
| 19 | lished under this Act or other applicable law; |
| 20 | and |
| 21 | "(4) prohibit or restrict the sale, transpor- |
| 22 | tation, offer for sale or transportation, or receipt for |
| 23 | transportation of any poultry or poultry products |
| 24 | that— |

| 1 | "(A) are capable of use as human food; |
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| 2 | and |
| 3 | "(B) exceed the regulatory limits, interim |
| 4 | limits, tolerances, or other standards estab- |
| 5 | lished under this Act or other applicable law for |
| 6 | human pathogens or other potentially harmful |
| 7 | substances. |
| 8 | "(d) Research and Regulatory Limits.— |
| 9 | "(1) Research on food safety.—The Sec- |
| 10 | retary, acting through the Under Secretary of Agri- |
| 11 | culture for Food Safety, shall conduct or support ap- |
| 12 | propriate research on food safety, including— |
| 13 | "(A) developing and reevaluating appro- |
| 14 | priate limits for human pathogens or other po- |
| 15 | tentially harmful substances that when found |
| 16 | on poultry and poultry products prepared in of- |
| 17 | ficial establishments may present a threat to |
| 18 | public health; |
| 19 | "(B) developing efficient, rapid, and sen- |
| 20 | sitive methods for determining and detecting |
| 21 | the presence of microbial contamination, chemi- |
| 22 | cal residues, and animal diseases that have an |
| 23 | adverse impact on human health; |
| 24 | "(C) conducting baseline studies on the |
| 25 | prevalence of human pathogens or other poten- |

| 1 | tially harmful substances in processing facili- |
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| 2 | ties; and |
| 3 | "(D) conducting risk assessments to deter- |
| 4 | mine the human pathogens and other poten- |
| 5 | tially harmful substances that pose the greatest |
| 6 | risk to human health. |
| 7 | "(2) Regulatory limits for human patho- |
| 8 | GENS AND OTHER HARMFUL SUBSTANCES.— |
| 9 | "(A) IN GENERAL.—Not later than 1 year |
| 10 | after the date of enactment of this section, the |
| 11 | Secretary of Health and Human Services shall |
| 12 | establish regulatory limits, to the maximum ex- |
| 13 | tent scientifically supportable, for human patho- |
| 14 | gens and other potentially harmful substances, |
| 15 | including heavy metals, that, when found as a |
| 16 | component of poultry or poultry products pre- |
| 17 | pared in official establishments, may present a |
| 18 | threat to public health. |
| 19 | "(B) RISK TO HUMAN HEALTH.—In estab- |
| 20 | lishing the regulatory limits, the Secretary of |
| 21 | Health and Human Services shall consider the |
| 22 | risk to human health, including the risk to chil- |
| 23 | dren, the elderly, individuals whose immune |
| 24 | systems are compromised, and other population |

subgroups, posed by consumption of the poultry

or poultry products containing the human pathogen or other potentially harmful substance.

"(C) FUNDING.—The Secretary of Agriculture shall annually transfer to the Secretary of Health and Human Services an amount, to be determined by the Secretaries, to defray the cost of establishing the regulatory limits.

"(e) Surveillance and Sampling Systems.—

"(1) Surveillance system.—In conjunction with the Director of the Centers for Disease Control and Prevention and the Commissioner of Food and Drugs, the Secretary shall develop and administer an active surveillance system for foodborne illness, that is based on a representative sample of the population of the United States, to assess more accurately the frequency and sources of human disease in the United States associated with the consumption of poultry and poultry products.

"(2) Sampling system.—

"(A) IN GENERAL.—Not later than 2 years after the date of enactment of this section, the Secretary shall establish a sampling system, using data collected under subsection (c)(2) and other sources, to analyze the nature, frequency

| 1 | of occurrence, and quantities of human patho- |
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| 2 | gens and other potentially harmful substances |
| 3 | in poultry and poultry products. |
| 4 | "(B) Information.—The sampling sys- |
| 5 | tem shall provide— |
| 6 | "(i) statistically valid monitoring, in- |
| 7 | cluding market basket studies, on the na- |
| 8 | ture, frequency of occurrence, and quantity |
| 9 | of human pathogens and other potentially |
| 10 | harmful substances in poultry and poultry |
| 11 | products available to consumers; and |
| 12 | "(ii) such other information as the |
| 13 | Secretary determines may be useful in as- |
| 14 | sessing the occurrence of human pathogens |
| 15 | and other potentially harmful substances |
| 16 | in poultry and poultry products. |
| 17 | "(C) Noncompliance.—If a sample is |
| 18 | found to exceed regulatory limits, interim lim- |
| 19 | its, tolerances, or standards established under |
| 20 | this Act or other applicable law, the Secretary |
| 21 | shall take action to prevent violative products |
| 22 | from entering commerce or to remove the viola- |
| 23 | tive products from the market. |
| 24 | "(f) Review and Consultation.— |

"(1) REVIEW.—The Secretary shall review, at 1 2 least every 2 years, all regulations, processes, proce-3 dures, and methods designed to limit and control human pathogens and other potentially harmful sub-5 stances present on or in poultry and poultry prod-6 ucts. The ongoing review shall include, as necessary, 7 epidemiologic and other scientific studies to ascertain the efficiency and efficacy of the regulations, 8 9 processes, procedures, and methods.

"(2) Consultation.—In carrying out paragraphs (1) and (3) of subsection (c), subsection (d), subsection (e)(1), and paragraph (1), the Secretary shall consult with the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, and the heads of such other Federal and State public health agencies as the Secretary considers appropriate.

19 "SEC. 31. HAZARD CONTROLS.

- 20 "(a) REGULATIONS.—
- "(1) ISSUANCE.—Not later than 1 year after the date of enactment of this section, the Secretary shall issue regulations that require an official estab-
- lishment to—

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| 1 | "(A) adopt processing controls that are |
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| 2 | adequate to protect public health; and |
| 3 | "(B) limit the presence and growth of |
| 4 | human pathogens and other potentially harmful |
| 5 | substances in poultry and poultry products pre- |
| 6 | pared in the establishment. |
| 7 | "(2) CONTENT.—The regulations shall— |
| 8 | "(A) set standards for sanitation; |
| 9 | "(B) set interim limits for biological, |
| 10 | chemical, and physical hazards, as appropriate; |
| 11 | "(C) require processing controls to ensure |
| 12 | that relevant regulatory standards are met; |
| 13 | "(D) require recordkeeping to monitor |
| 14 | compliance; |
| 15 | "(E) require sampling to ensure that proc- |
| 16 | essing controls are effective and that regulatory |
| 17 | standards are being met; and |
| 18 | "(F) provide for agency access to records |
| 19 | kept by official establishments and submission |
| 20 | of copies of the records to the Secretary as the |
| 21 | Secretary considers appropriate. |
| 22 | "(3) PUBLIC ACCESS.—Public access to records |
| 23 | that relate to the adequacy of measures taken by an |
| 24 | official establishment to protect the public health, |
| 25 | and to limit the presence and growth of human |

- pathogens and other potentially harmful substances,
 shall be subject to section 552 of title 5, United
 States Code.

 "(4) PROCESSING CONTROLS.—The Secretary
 may, as the Secretary considers necessary, require
 any person with responsibility for, or control over,
- any poultry or poultry products intended for human consumption to adopt processing controls, if the processing controls are needed to ensure the protec-
- tion of public health.
- 11 "(b) Advisory Board.—On the issuance of regula-
- 12 tions under subsection (a), the Secretary shall convene an
- 13 advisory board on meat and poultry safety in accordance
- 14 with section 502(b) of the Federal Meat Inspection Act.
- 15 "(c) Labeling.—Notwithstanding any other provi-
- 16 sion of this Act, if the Secretary discontinues carcass-by-
- 17 carcass inspection of poultry, the 'USDA Inspected for
- 18 Wholesomeness' seal, or a similar seal, shall not be affixed
- 19 to any poultry and poultry products derived from the poul-
- 20 try prepared in any official establishment.
- 21 "SEC. 32. VOLUNTARY GUIDELINES FOR RETAIL ESTAB-
- 22 LISHMENTS.
- 23 "(a) STANDARDS.—
- 24 "(1) IN GENERAL.—In consultation with rep-
- resentatives of States, the Conference for Food Pro-

| 1 | tection, the Association of Food and Drug Officials, |
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| 2 | and Federal agencies, the Secretary shall establish |
| 3 | minimum standards for the handling, processing, |
| 4 | and storage of poultry and poultry products at retail |
| 5 | stores, restaurants, and similar types of retail estab- |
| 6 | lishments (collectively referred to in this section as |
| 7 | 'retail establishments'). |
| 8 | "(2) CONTENT.—The standards shall— |
| 9 | "(A) be designed to ensure that poultry |
| 10 | and poultry products sold by the retail estab- |
| 11 | lishments are safe for human consumption; |
| 12 | "(B) be based on the principles of preven- |
| 13 | tive controls; and |
| 14 | "(C) include— |
| 15 | "(i) safe food product processing and |
| 16 | handling practices for retail establish- |
| 17 | ments, including time and temperature |
| 18 | controls on poultry and poultry products |
| 19 | sold by the establishments; |
| 20 | "(ii) equipment handling practices, in- |
| 21 | cluding standards for the cleaning and |
| 22 | sanitization of food equipment and uten- |
| 23 | sils; |
| 24 | ''(iii) minimum personnel hygiene re- |
| 25 | quirements; and |

"(iv) requirements for the use of temperature warning devices on raw poultry or poultry products to alert consumers to inadequate temperature controls.

"(b) Guidelines.—

- "(1) ISSUANCE.—Not later than 18 months after the date of enactment of this section, the Secretary, after notice and opportunity for comment, shall issue guidelines for retail establishments that offer poultry and poultry products that include the standards established under subsection (a).
- "(2) Compliance.—Not later than 18 months after the date of enactment of this section, the Secretary shall issue a final regulation defining the circumstances that constitute substantial compliance by retail establishments with the guidelines issued under paragraph (1). The regulation shall provide that there is not substantial compliance if a significant number of retail establishments have failed to comply with the guidelines.

"(3) Report.—

"(A) IN GENERAL.—Not later than 3 years after the date of enactment of this section, the Secretary shall issue a report to Congress on actions taken by retail establishments to comply

with the guidelines. The report shall include a determination of whether there is substantial compliance with the guidelines.

- "(B) SUBSTANTIAL COMPLIANCE.—If the Secretary determines that there is substantial compliance with the guidelines, the Secretary shall issue a report and make a determination in accordance with subparagraph (A) not less than every 2 years.
- "(C) No substantial compliance.—If the Secretary determines that there is not substantial compliance with the guidelines, the Secretary shall (at the time the determination is made) issue proposed regulations requiring that retail establishments comply with the guidelines. The Secretary shall issue final regulations imposing the requirement not later than 180 days after issuance of any proposed regulations. Any final regulations shall become effective 180 days after the date of the issuance of the final regulations.
- "(c) Enforcement.—A State may bring, in the name of the State and within the jurisdiction of the State, a proceeding for the civil enforcement, or to restrain a violation, of final regulations issued pursuant to subsection

- 1 (b)(3)(C) if the food that is the subject of the proceeding
- 2 is located in the State.

3 "SEC. 33. LIVESTOCK TRACEBACK.

- 4 "(a) In General.—
- "(1) IDENTIFICATION.—For the purpose of un-5 derstanding the nature of foodborne illness and 6 7 minimizing the risks of foodborne illness from poultry and poultry products distributed in commerce, 8 9 the Secretary shall, as the Secretary considers necessary, prescribe by regulation that poultry pre-10 11 sented for slaughter for human food purposes be 12 identified in a manner prescribed by the Secretary to enable the Secretary to trace each poultry to any 13 14 premises at which the poultry has been held for such 15 period prior to slaughter as the Secretary considers 16 necessary to carry out this Act.
 - "(2) PROHIBITION OR RESTRICTION ON ENTRY.—The Secretary may prohibit or restrict entry into any slaughtering establishment inspected under this Act of any poultry not identified as prescribed by the Secretary.
- 22 "(b) RECORDS.—

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23 "(1) IN GENERAL.—The Secretary may require 24 that a person required to identify poultry pursuant 25 to subsection (a) maintain accurate records, as pre-

- scribed by the Secretary, regarding the purchase, sale, and identification of the poultry.
- "(2) Access.—A person subject to paragraph (1) shall, at all reasonable times, on notice by a duly authorized representative of the Secretary, afford the representative access to the place of business of the person and an opportunity to examine the
- 9 "(3) DURATION.—Any record required to be 10 maintained under this subsection shall be main-11 tained for such period of time as the Secretary pre-12 scribes.

records of the person and copy the records.

- "(c) False Information.—No person shall falsify or misrepresent to the Secretary or any other person any information concerning the premises at which any poultry were held.
- 17 "(d) Maintenance of Records.—No person shall,
- 18 without authorization from the Secretary, alter, detach, or
- 19 destroy any records or other means of identification pre-
- 20 scribed by the Secretary for use in determining the prem-
- 21 ises at which were held any poultry.
- "(e) Human Pathogens or Other Harmful Sub-
- 23 STANCES.—

- "(1) IDENTIFICATION OF SOURCE.—If the Sec-
- retary finds any human pathogen or any other po-

tentially harmful substance in any poultry at the time the poultry is presented for slaughter or in any poultry or poultry products prepared in an official establishment and the Secretary finds that there is a reasonable probability that human consumption of any poultry or poultry product containing the human pathogen or other potentially harmful substance presents a threat to public health, the Secretary may take such action as the Secretary considers necessary to determine the source of the human pathogen or other potentially harmful substance.

"(2) Action.—If the Secretary identifies the source of any human pathogen or other potentially harmful substance referred to in paragraph (1), the Secretary may prohibit or restrict the movement of any poultry or poultry products, or any other article from any source of the human pathogen or other potentially harmful substance until the Secretary determines that the human pathogen or other potentially harmful substance at the source no longer presents a threat to public health.

"(f) Producers and Handlers.—

"(1) USE OF METHODS.—The Secretary shall use any means of identification and recordkeeping methods utilized by producers or handlers of poultry

whenever the Secretary determines that the means 1 2 of identification and recordkeeping methods will enable the Secretary to carry out this section. 3 "(2) COOPERATION.—The Secretary may cooperate with producers or handlers of poultry in 5 which any human pathogen or other potentially 6 harmful substance described in subsection (e)(1) is 7 found, to develop and carry out methods to limit or 8 9 eliminate the human pathogen or other potentially 10 harmful substance at the source. "SEC. 34. NOTIFICATION AND RECALL OF NONCONFORM-12 ING ARTICLES. "(a) NOTIFICATION.—Any person preparing poultry 13 or poultry products for distribution in commerce who ob-14 tains knowledge that provides a reasonable basis for believing that any poultry or poultry products— 17 "(1) are unsafe for human consumption, adul-18 terated, or not produced in accordance with section 19 30(a); or "(2) are misbranded; 20 shall immediately notify the Secretary, in such manner 21 and by such means as the Secretary may by regulation prescribe, of the identity and location of the articles. 23

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"(b) RECALL.—

| 1 | "(1) IN GENERAL.—If the Secretary finds, on |
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| 2 | notification or otherwise, that any poultry or poultry |
| 3 | products— |
| 4 | "(A) are unsafe for human consumption, |
| 5 | adulterated, or not produced in accordance with |
| 6 | section 30(a); or |
| 7 | "(B) are misbranded; |
| 8 | the Secretary shall by order require any person en- |
| 9 | gaged in the processing, handling, transportation, |
| 10 | storage, importation, distribution, or sale of poultry |
| 11 | or poultry products to immediately cease any dis- |
| 12 | tribution of the poultry or poultry products, and to |
| 13 | recall the poultry or poultry products from commer- |
| 14 | cial distribution and use, if the Secretary determines |
| 15 | that there is a reasonable probability that the prod- |
| 16 | uct is unsafe for human consumption, adulterated, |
| 17 | or misbranded, unless the person is engaged in a |
| 18 | voluntary recall of the poultry or poultry products |
| 19 | that the Secretary considers adequate. |
| 20 | "(2) Order.—The order shall— |
| 21 | "(A) include a timetable during which the |
| 22 | recall shall occur; |
| 23 | "(B) require periodic reports by the person |
| 24 | to the Secretary describing the progress of the |
| 25 | recall; and |

"(C) require notice to consumers to whom the articles were, or may have been, distributed as to how the consumers should treat the article.

"(c) Informal Hearing.—

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- "(1) IN GENERAL.—The order shall provide any person subject to the order with an opportunity for an informal hearing, to be held not later than 5 days after the date of issuance of the order, on the actions required by the order.
- "(2) VACATION OF ORDER.—If, after providing an opportunity for the hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.
- "(d) Judicial Recall.—A district court of the
 United States may order any person engaged in the processing, handling, transportation, storage, importation, distribution, or sale of poultry or a poultry product to recall
 the poultry or product if the court finds that there is a
 reasonable probability that the poultry or poultry product
 is unsafe for human consumption, adulterated, or mis-

branded.

1 "SEC. 35. REFUSAL OR WITHDRAWAL OF INSPECTION.

- 2 "(a) IN GENERAL.—The Secretary may, for such pe-
- 3 riod or indefinitely as the Secretary considers necessary
- 4 to carry out this Act, refuse to provide, or withdraw, in-
- 5 spections under this Act with respect to any official estab-
- 6 lishment if the Secretary determines, after opportunity for
- 7 a hearing is accorded to the applicant for, or recipient of,
- 8 the service that the applicant or recipient, or any person
- 9 connected with the applicant or recipient, has repeatedly
- 10 failed to comply with this Act.
- 11 "(b) Inspections Pending Review.—The Sec-
- 12 retary may direct that, pending opportunity for an expe-
- 13 dited hearing in the case of any refusal or withdrawal of
- 14 inspections and the final determination and order under
- 15 subsection (a) and any judicial review of the determination
- 16 and order, inspections shall be denied or suspended if the
- 17 Secretary considers the action necessary in the public in-
- 18 terest in order to protect the health or welfare of consum-
- 19 ers or to ensure the safe and effective performance of offi-
- 20 cial duties under this Act.
- 21 "(c) Judicial Review.—
- 22 "(1) IN GENERAL.—The determination and
- order of the Secretary with respect to refusal or
- 24 withdrawal of inspections under this section shall be
- final and conclusive unless the applicant for, or re-
- cipient of, inspections files an application for judicial

| 1 | review not later than 30 days after the effective date |
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| 2 | of the order. |
| 3 | "(2) Inspections pending review.—Inspec- |
| 4 | tions shall be refused or withdrawn as of the effec- |
| 5 | tive date of the order pending any judicial review of |
| 6 | the order unless the Secretary or the Court of Ap- |
| 7 | peals directs otherwise. |
| 8 | "(3) Venue; record.—Judicial review of the |
| 9 | order shall be— |
| 10 | "(A) in the United States Court of Appeals |
| 11 | for the circuit in which the applicant for, or the |
| 12 | recipient of, inspections has the principal place |
| 13 | of business of the applicant or recipient or in |
| 14 | the United States Court of Appeals for the Dis- |
| 15 | trict of Columbia Circuit; and |
| 16 | "(B) based on the record on which the de- |
| 17 | termination and order are based. |
| 18 | "(4) Process.—Section 204 of the Packers |
| 19 | and Stockyards Act, 1921 (7 U.S.C. 194), shall be |
| 20 | applicable to appeals taken under this section. |
| 21 | "(d) Additional Authority.—This section shall be |
| 22 | in addition to, and not derogate from, any provision of |
| 23 | this Act for refusal, withdrawal, or suspension of inspec- |
| 24 | tions under this Act. |

| 1 | "SEC. 36. CIVIL PENALTIES. |
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| 2 | "(a) In General.— |
| 3 | "(1) ASSESSMENT.—A person who violates any |
| 4 | of sections 30 through 37, a regulation issued under |
| 5 | any of the sections, or an order issued under sub- |
| 6 | section (b) or (d) of section 34 may be assessed a |
| 7 | civil penalty by the Secretary of not more than |
| 8 | \$100,000 for each day of violation. |
| 9 | "(2) Separate violation.—Each offense de- |
| 10 | scribed in paragraph (1) shall be considered to be a |
| 11 | separate violation. |

- "(3) Notice and opportunity for hear-ING.—No penalty may be assessed against a person under this section unless the person is given notice and an opportunity for a hearing on the record before the Secretary in accordance with sections 554 and 556 of title 5, United States Code.
- "(4) Amount.—The amount of the civil penalty shall be assessed by the Secretary by written order, taking into account the gravity of the violation, the degree of culpability, and any history of prior offenses. The amount may be reviewed only as provided in subsection (b).
- "(b) REVIEW.— 24
- "(1) IN GENERAL.—A person against whom a 25 violation is found and a civil penalty assessed by 26

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- order of the Secretary under subsection (a) may ob-tain review of the order in the United States Court of Appeals for the circuit in which the party resides or has a place of business or in the United States Court of Appeals for the District of Columbia Cir-cuit by filing a notice of appeal in the court not later than 30 days after the date of the order and by simultaneously sending a copy of the notice by cer-tified mail to the Secretary.
 - "(2) RECORD.—The Secretary shall promptly file in the court a certified copy of the record on which the violation was found and the penalty assessed.
 - "(3) FINDINGS.—The findings of the Secretary shall be set aside only if found to be unsupported by substantial evidence on the record as a whole.

"(c) CIVIL ACTION TO RECOVER ASSESSMENT.—

"(1) IN GENERAL.—If a person fails to pay an assessment of a civil penalty after the penalty has become a final and unappealable order, or after the appropriate Court of Appeals has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General, who shall institute a civil action to recover the amount as-

- sessed in any appropriate district court of the United States.
- 3 "(2) Scope of review.—In a recovery action
- 4 under paragraph (1), the validity and appropriate-
- 5 ness of the order of the Secretary imposing the civil
- 6 penalty shall not be subject to review.
- 7 "(d) DISPOSITION OF AMOUNTS.—All amounts col-
- 8 lected under this section shall be paid into the Treasury
- 9 of the United States.
- 10 "(e) Equitable Relief.—
- 11 "(1) RELATIONSHIP TO OTHER ACTIONS.—
- Nothing in this Act requires the Secretary to report
- for criminal prosecution, or for the institution of an
- injunction or other proceeding, a violation of this
- 15 Act, if the Secretary believes that the public interest
- will be adequately served by assessment of civil pen-
- 17 alties.
- 18 "(2) Modification of Penalty.—The Sec-
- retary may compromise, modify, or remit, with or
- without conditions, any civil penalty assessed under
- 21 this section.
- 22 "SEC. 37. WHISTLEBLOWER PROTECTION.
- 23 "(a) IN GENERAL.—No person subject to this Act
- 24 may harass, prosecute, hold liable, or discriminate against
- 25 any employee or other person because the person—

- "(1) is assisting or demonstrating an intent to assist in achieving compliance with any Federal or State law (including a rule or regulation);
 - "(2) is refusing to violate or assist in the violation of any Federal or State law (including a rule or regulation); or
- 7 "(3) has commenced, caused to be commenced, 8 or is about to commence a proceeding, has testified 9 or is about to testify at a proceeding, or has assisted 10 or participated or is about to assist or participate in 11 any manner in such a proceeding or in any other ac-12 tion to carry out the functions or responsibilities of any agency, office, or unit of the Department of Ag-13 14 riculture.
- "(b) PROCEDURES AND PENALTIES.—The procedures and penalties applicable to prohibited acts under subsection (a) shall be governed by the applicable provisions of section 31105 of title 49, United States Code.
- "(c) BURDENS OF PROOF.—The legal burdens of proof with respect to prohibited acts under subsection (a) shall be governed by the applicable provisions of sections
- 22 1214 and 1221 of title 5, United States Code.".

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